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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/748,793	12/26/2000	Ruedi H. Aebersold	P-IS 4534	3321
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23601 7590 10/15/2002

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 10/15/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/748,793

Applicant(s)

AEBERSOLD ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 24-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>12 & 13</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed 7/26/02 in Paper No. 10 is acknowledged and entered.

Claims 1 and 13 are amended. Claims 1-43 are pending.

Election/Restrictions

2. Applicant's election with traverse of Group I (Claims 1-23) in Paper No. 10 is acknowledged. The traversal is on the ground(s) that Group II (Claims 24-43) should be joined with Group I for the claims grouped separately are not independent and distinct and therefore, the examination of the entire application cannot constitute a serious burden to search all claims. These arguments have been fully considered but are not found to be persuasive for the reasons below.

First, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct inventions.

Second, MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term "distinct" is defined to mean that two or more subjects as disclosed are related, for example, as product and method of use, but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.1). In the instant situation, the inventions of Group I and Group II are drawn to distinct inventions, which are related as separate

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methods capable of separate functions. Restrictions between the inventions are deemed to be proper for the reason previously set forth.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. Group I (Claims 1-23) is classified in class 436, subclass 149 and Group II (Claims 24-43) is classified in class 436, subclass 173. In the instant case a burden has been established in showing that the inventions of Groups I and II are classified separately necessitating different searches of issued US Patents in different subclasses. However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because for example a patentability determination for Group II would involve a determination of the patentability of the method of generating a polypeptide identification index while a patentability determination for Group I would involve a consideration of the patentability of the method of identifying a polypeptide. These considerations are very different in nature. Additionally, it is submitted that the inventions of Groups I and II have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group.

For these reasons, the restriction requirement is deemed to be proper and is therefore made **FINAL**.

3. Claims 24-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 10.

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4. This application contains claims 24-43 are drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

7. Claims 13-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear in Claim 13 what is the correlation between the method step c) of identifying the polypeptide and the method step d) of quantitating the amount of identified polypeptide. In what ways is the quantitating step related to the method of identifying a polypeptide? Further, from the specification (pg. 6, lines 16-31 and pg. 7, lines 12-28) the method of identifying the

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polypeptide involves different method steps from the method of quantitating the polypeptide. In quantitating the polypeptide, isotopic labels and internal standard are used.

Claim Rejections - 35 USC § 102

8. Claims 1-2 and 8-12 rejected under 35 U.S.C. 102(b) as being anticipated by Yates, III (*J. Mass Spectrom.*; 33(1):1-19; 1998) or Link et al. (*Nat. Biotechnol.*; 17(7):676-682; 1999) for reason of record in paragraph 9 of the previous Office Action.

Claim Rejections - 35 USC § 103

9. Claims 3, 13-14, and 20-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Yates, III (*J. Mass Spectrom.*; 33(1):1-19; 1998) or Link et al. (*Nat. Biotechnol.*; 17(7):676-682; 1999) in view of Mann (*Nat. Biotechnol.*; 17(10):954-955; 1999) or Gygi et al. (*Nat. Biotechnol.*; 17(10):994-999; 1999) for reason of record in paragraph 13 of the previous Office Action..

10. Claims 4-8 and 15-19 rejected under 35 U.S.C. 103(a) as being unpatentable over Yates, III (*J. Mass Spectrom.*; 33(1):1-19; 1998) or Link et al. (*Nat. Biotechnol.*; 17(7):676-682; 1999) in view of Masselon et al. (*Anal. Chem.*; 72:1918-1924; 2000) for reason of record in paragraph 14 of the previous Office Action.

Response to Arguments

11. Applicant's arguments filed 7/26/02 have been fully considered but they are not persuasive. Applicant alleges that there is a distinction between "empirical determined characteristic" and "predicted values". The currently claimed invention uses the annotated polypeptide index (database) that is associated with empirical by determined characteristics and Yates and Link et al. use a database that is associated with predicted values. It is the examiner position that there is no distinction between "empirical^{by} determined characteristics" and "predicted values". In fact the Webster's II New Riverside University Dictionary (*The Riverside Publishing Company, 1984*), defines "empirical" as a) relying upon or gained from experiment or observation; b) capable of proof or verification by means of experiment or observation; c) relying solely on practical experience and without regard for theory or system. In both Yates and Link et al., the predicted values are observed values that have been verified by means of experiment (Yates: pg. 7, right column, lines 58-64; Link: pg. 676, right column, lines 9-18). Therefore, there is no distinction between "empirical^{by} determined characteristics" and "predicted values" because "predicted values" are "empirical^{by} determined characteristic" that have been verify^{ied}. Yates or Link et al. anticipated^{ed} the currently claimed invention.

12. Applicant contend that the combination of Yates or Link et al. in combination of with Mann or Gygi et al. is not obvious because Yates or Link et al. do not teach the use of an annotated polypeptide index (database). It is the examiner position that the combination of Yates or Link et al. in combination of with Mann or Gygi et al. is obvious because Yates or Link et al. do teach the use of an annotated polypeptide index in the method for identifying a polypeptide.

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In the method for identifying a polypeptide disclosed by Yates or Link et al., the database use^d by Yates or Link et al. anticipate^s the annotated polypeptide index of the currently claimed invention as discussed above.

13. In regard to the rejection of claims 4-8 and 15-19, applicant' argue that the mass accuracy recited claims 4-8 and 15-19 with increased ppm values are directed to decreasing mass accuracy. It is the examiner position that currently claims 4-8 and 15-19 do not claim that the increase ppm values are directed to decreasing mass accuracy. What is being claimed in claims 4-8 and 15-19 is that the fragment mass is determined at an accuracy at a range of ppm. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Therefore, Masselon et al. in combination with Yates and Link et al. does render the claimed methods obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

mct
October 8, 2002

Mary E. Ceperley
MARY E. CEPERLEY
PRIMARY EXAMINER
AU 1641